

M890911
209

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

September 18, 1989

MEMORANDUM FOR: James M. Taylor
Acting Executive Director for Operations

FROM: Samuel J. Chilk, Secretary

SUBJECT: STAFF REQUIREMENTS - AFFIRMATION/DISCUSSION
AND VOTE, 10:00 A.M., MONDAY, SEPTEMBER 11,
1989, COMMISSIONERS' CONFERENCE ROOM, ONE
WHITE FLINT NORTH, ROCKVILLE, MARYLAND
(OPEN TO PUBLIC ATTENDANCE)

I. SECY-89-276 - Motion for Reconsideration Filed by Joseph J. Macktal

The commission, by a 4-0 vote, approved an order responding to an August 18, 1989, motion by Joseph J. Macktal requesting that the commission reconsider its decision in CLI-89-14 where it declined to disqualify itself from deciding any future matters involving Mr. Macktal. The order denied the motion to reconsider.

(Subsequently, on September 11, 1989, the Secretary signed the order.)

II. SECY-89-194 - Amendments to 10 CFR Part 34: Safety Requirements for Industrial Radiographic Equipment

The commission, by a 4-0 vote, approved amendments to 10 CFR Part 34 which apply to industrial radiography. The amendments are intended to reduce radiation exposure to both radiography personnel and the general public from the use of radiographic equipment. The Commission also modified its enforcement policy to add a specific example to put licensees on notice that the failure to implement the requirements for dosimetry and equipment may be considered a violation of significant regulatory concern.

210

The Commission also agreed to make the rule effective six months after publication and agreed to the attached modifications.

The rule should be modified as noted, reviewed by the Regulatory Publication Branch for conformance with the requirements of the Federal Register and returned for signature and publication.

(EDO)

(SECY Suspense: 10/6/89)

Attachment:
As stated

cc: Chairman Carr
Commissioner Roberts
Commissioner Rogers
Commissioner Curtiss
OGC
GPA
PDR - Advance
DCS - P1-24

[7590-01]

211

EFFECTIVE DATE: (6 months from date of publication). The

incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of

FOR FURTHER INFORMATION CONTACT: Dr. Donald O. Nellis, Radiation Pro

tec-
tion and Health Effects Branch, Division of Regulatory Applications,
Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission,
Washington, DC 20555, telephone (301) 492-3628.

SUPPLEMENTARY INFORMATION:

CONTENTS

Background
Radiography Related Overexposures
Previous Regulatory Initiatives
Public Comments
Finding of No Significant Environmental Impact: Availability
Paperwork Reduction Act Statement
Regulatory Analysis
Regulatory Flexibility Analysis
Backfit Analysis

List of Subjects
Appendix A - Regulatory Flexibility Analysis

On March 15, 1988, the Nuclear Regulatory Commission published for
public comment a proposed rule [53 FR 8460] that would require NRC lic-
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sees to use radiographic exposure devices that meet the criteria speci-
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fied in American National Standard N432, "Radiological Safety for the
05/22/89 2 Enclosure A

[7590-01]

212

device; however, some devices, such as the so called "pipeliner," utilize
a shutter to allow the radiation beam to exit from the device while the
source remains in a shielded position within the device.

The general procedure used is as follows: First, a radiation sensitive
film is positioned over the area of interest on the item to be
examined. Then a radiography exposure device or camera (which contains
a sealed gamma-ray emitting source within a radiation shield) is placed
nearby. A flexible hollow tube called a "guide tube" is connected to

the front of the device, and the other end of the guide tube (to which an exposure head is attached), is positioned opposite the film on the item to be examined. Next, on the back of the device, a "control cable" is connected to the radiation source assembly, sometimes called a "pigtail" (a short length of wire with the source fastened on one end and a connector for the control cable on the other). Use of the "pigtail" allows the connection to be made without directly exposing the radiographer because the source itself remains in its shielded position within the device while the connection is being made. Lastly, a hollow tube through which the control cable moves is connected to the back of the device. The control cable and its tube are then unreeled until the cranking device for operating the cable is approximately ten to twenty feet from the device. This distance provides radiation protection for the radiographer. Next, the radioactive source is cranked or pushed from the radiographic device to the end of the guide tube. This causes the gamma-rays from the source to penetrate the item under examination and expose the film. At the end of the desired exposure time the source is cranked back into the device. A survey is made with a radiation detection device to ensure that the source assembly is in its shielded position. The source is then secured in

06/05/89

4

Enclosure A

[7590-01]

213

this position and the film is retrieved for development. The radiographer is then ready to proceed with the next exposure. In some instances, what is referred to as "real time" radiography is performed. This merely involves replacing the film with remotely operated TV fluoroscopic equ

ip-
ment, solid state, or other suitable detection equipment that produces
an
image in real time without requiring development of a film.

Although the described procedure appears straightforward, and most
radiography is performed safely, radiation overexposures to radiograph
ers
and occasionally to the general public occur. Accidental radiation ov
er-
exposures to both radiographers and the public have concerned both the
NRC
and the Agreement States because the radiation levels of the radioacti
ve
sources used in industrial radiography are sufficient to cause serious
injury or death.

Industrial radiography performed in the field is of most concern.
Unlike many other applications of ionizing radiation which are rigidly
controlled and remote from the public, industrial radiography involves
the use of high activity sources, sometimes in close proximity to the
general public. The work, which is often only under control of the
radiographer, is generally performed under production pressure and is
often performed in adverse weather and environmental conditions. Such
conditions can lead to both equipment failure and failure to follow pr
o-
per safety procedures (e.g., failure to perform the required radiation
survey or allowing assistant radiographers to perform the radiography
themselves without the direct supervision of the more highly trained a
nd
skilled radiographer). Such failures, either singly or in combination
,
occasionally lead to radiation overexposures. Some of the failures of

05/22/89

5

Enclosure A

[7590-01]
214

radiography licensees to follow NRC requirements have been docu
mented in
a recent NRC information notice.^1

The NRC has been concerned about the number of radiation overexposures
among radiographers for several years and has completed, has underway,
or
is considering, actions intended to reduce the frequency of the overex

po-
sures. These actions include: (a) development of a training manual
for
radiography personnel to help ensure that they understand the need for
,
and the application of, good radiation protection practices,2 (b) deve
lop-
ment of NRC requirements to ensure that radiographers are adequately
trained and are aware of their direct responsibility for safety perfor
mance,
(c) increased inspection of workers performing actual radiography oper
ations,
(d) publication of guidance for reporting events to ensure that these
reports include clear information concerning equipment failures when
appropriate, and (e) the establishment of safety requirements for radi
ographic
equipment.

1^ NRC Information Notice No. 87-45: "Recent Safety Related Violatio
ns of
NRC Requirements by Industrial Radiography Licensees," September 25,
1987. Single copies of this information notice may be obtained by
telephone by interested persons at (301) 634-3273.

06/05/89 6 Enclosure A

[7590-01] 215

Radiography Related Overexposures

NRC licensees are required to report radiation overexposures to the
NRC. Based on overexposures reported to NRC, over the decade ending i
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1984 industrial radiography accounted for 1) more than one-half of
the overexposures greater than 5 rems to the whole body or 75 rems to
the extremities and 2) almost 60% of the overexposures greater than 25
rems
to the whole body and 375 rems to the extremities. Over this same per
iod,
radiography accounted for almost 25% of all overexposures reported by
NRC licensees.32-

During the years 1979 through 1983, radiographer overexposures
reported to the NRC and Agreement States combined accounted for 18% of
all occupational overexposures, although radiographers represented onl
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M890911.txt

4% of all radiation workers. Many additional incidents may have occurred which had the potential for serious overexposure from the high-intensity relatively high-energy gamma-ray sources used. but did not require reporting.

Three incidents in foreign countries where children or adults have found lost radiography sources and have died from overexposure illustrate the extreme hazard potential involved in radiography overexposures. In other cases involving radiography sources, overexposures have caused acute effects such as burns and necrosis of body tissues. Some examples of incidents which show the extreme hazard potential are:

(1) 1979, California: The source assembly was improperly connected or became disconnected and was cranked out of the end of the guide tube and fell to the ground. No radiation survey was made. An individual

23^ The year 1984 is the most recent year for which complete exposure data has been tabulated for all NRC licensees.

05/22/89 7 Enclosure A

[7590-01] 216

exposures of 22, 7 and 0.6 rem respectively. One unbadged employee and six members of the general public received doses believed to be less than 0.5 rem each.

NRC studies of radiography exposure data indicate that radiography equipment problems contribute to approximately 40% of all reported overexposures. Equipment problems of the following types frequently play a contributing role:

(1) The source moves out of the shielded position after being cranked back into the device and before being locked, or the locking device is defective and fails to retain the source in the proper position.

(2) The source assembly is not properly connected or becomes disconnected, so that while it may be cranked out of its shielded position in the device, it cannot be retracted and remains in the guide tube.

(3) The source assembly is not properly connected or becomes disconnected and is cranked out through the end of the guide tube and drops to the ground.

(4) The source becomes stuck in the guide tube due to damage to the guide tube or due to fraying of the control cable.

All of these conditions could be recognized by performing a radiation survey after each radiographic exposure (to verify that the source is properly returned to its shielded position within the radiography device). Radiographers are required by the regulations in 10 CFR 34.43(b) to perform such a survey. In many cases, however, the radiation survey instrument is not used, is used incorrectly, or is defective. In Item (1) above, any overexposure would typically involve only the radiographers. In the remaining three items there is considerable potential for exposure to the public as well as to radiography personnel since the

05/22/89 9 Enclosure A

[7590-01] 217

was formed to draft recommendations for improving radiography safety. Four task forces were subsequently established by the steering committee to address various aspects of the problem. These task force assignments were: Training and Certification. Radiographic Equipment Design Safety, Inspection, and Collection and Analysis of Incident Data.

In 1982, the NRC published a training manual for industrial radiographers,²³ and in 1984 the equipment safety task force presented its recommendations on performance criteria for radiographic exposure devices⁴ to the Radiography Steering Committee and urged that the recommendations be

M890911.txt

added to the rules as soon as possible. These recommendations include many of the performance criteria specified in the consensus standard together with additional criteria.

The voluntary consensus standard ANSI N432, issued in 1981, is currently under review for possible revision. The revision is expected to incorporate many of the performance requirements in the international standard, ISO 3999, "Apparatus for Gamma Radiography Specification." Some of the performance requirements expected to be incorporated in the revised standard are the same as those recommended by the equipment task force. Publication of the revision of ANSI N432 as a final industry

23^ NUREG/BR-0024, "Working Safely in Gamma Radiography," S. A. McGuire and C. A. Peabody, 1982. Copies of NUREG/BR-0024 may be purchased from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20013-7082. Copies are also available from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161. A copy is available for inspection or copying for a fee in the NRC Public Document Room, 2120 L Street NW., Lower Level, Washington, DC 20037.

4^ "Radiographic Equipment Safety Performance Criteria," D. Honey (CA), R. Ratliff (TX), R. Wascom (LA), S. Baggett, and A. Tse (NRC), April 30, 1984. For a copy of this report see paragraph heading For Further Information Contact:

06/05/89 11 Enclosure A

[7590-01] 218

standard may take several years. When issued, NRC will consider if additional rulemaking is appropriate or necessary to incorporate the standard.

While American National Standard N432 has been available since 1981, i

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does not appear that all manufacturers are actually using the consensus
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standard nor does it appear that its provisions have been uniformly or
completely implemented by radiography equipment manufacturers. Also,
some
of the equipment currently in use may have been manufactured prior to
publication of the standard and may not meet its provisions. As a result,
it is assumed that the voluntary consensus standard has had little effect
on reducing the number or severity of radiography overexposures. Further,
some of the equipment improvements recommended by the Radiography Steering
Committee are not included in the standard.

NRC studies indicated that some 40% of the overexposure incidents involved
equipment problems. Therefore, regulatory action is needed at this time in
order to reduce the number of radiography incidents and to prevent additional
serious overexposures that are possible given the high radiation output of the
sources used in this industry.

The Radiography Steering Committee also suggested that one means of
reducing radiographer overexposures caused by the failure to detect the
return of the source to its properly shielded position in the radiographic
exposure device, would be to require that radiographers wear alarm meters.
These are radiation detection devices that provide an audible alarm at
some preset dose or dose-rate or both.

05/22/89 12 Enclosure A

[7590-01] 219

Audible-alarm meters are especially useful when radiographers cannot
hold survey meters because they need both hands to perform a job or when
they cannot continually look at the survey meter because the operation

M890911.txt

they are performing requires them to look elsewhere. Alarm meters are not to be substituted for a radiation survey meter but are to be considered a complementary warning device. The use of audible-alarm meters is now a requirement for radiographer trainees in Canada and has proved useful according to Canadian officials.

NRC Regulatory Guide 8.28⁵ "Audible-Alarm Dosimeters" discusses a program for the appropriate use of audible-alarm meters. The term "audible-alarm dosimeters" as used in this guide refers to pocket sized radiation detectors that alarm when either a preset integrated exposure or a preset exposure rate is reached. They provide an audible warning to a radiographer when he or she is approaching an exposed source, so that actions can be taken immediately to minimize unnecessary radiation exposure. These dosimeters are used in nuclear power plants on a relatively widespread basis. Few, however, are used in the radiography industry in the United States. Alarm meters are considered reliable and hold up well with proper use. The steering committee recommended that audible-alarm rate meters be required in the final rule.

⁵Regulatory Guide 8.28 is available for inspection at the Commission's Public Document Room, 2120 L Street NW., Lower Level, Washington, DC 20037. Copies of the Regulatory Guide may be purchased by calling (202)275-2060 or by writing to the Superintendent of Documents, U.S. Government Printing Office, Post Office Box 37082, Washington, DC 20013-7082.

06/05/89 13 Enclosure A

[7590-01] 220

Public Comments

M890911.txt

The NRC received a total of eighty-eight public responses to the proposed rule. Some of the responses were duplicates, some were requests for an extension of the comment period, and some were not relevant to the proposed rule. The number of valid responses to the proposed rule was sixty-eight. The proposed amendments involved twenty-six separate items and the average responder commented on at least ten of the items. In addition, the American Society for Non-Destructive Testing, Inc. submitted the results from a survey of 399 of its members regarding the proposed safety requirements for industrial radiographic equipment. All of the comments have been considered in preparing the final rule, as described in the Analysis of Comments document which is available for review and copying for a fee at the NRC Public Document Room located at 2120 L Street NW, Lower Level, Washington, DC 20037.

Most of those commenting indicated that they approved of the NRC goals for improving the safety of radiography equipment but many expressed differences of opinion on methods of obtaining these goals. Of the twenty-six items proposed, comments were equally divided on two, opposed on nine, and in favor on fifteen. The principal comments and the NRC response for each of the proposed items are given below.

Section 34.20(a) Radiographic Equipment Must Meet the Requirements of ANSI N432.

Comment:

Twenty-four comments responses were received on this provision, with the comments essentially divided. The main issue raised by commenters

06/05/89 14 Enclosure A

[7590-01] 221

opposed to the requirement involved the maximum allowed radiation level

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specified in the ANSI standard. Many felt that the added shielding
required to meet

06/05/89 14a Enclosure A

[7590-01] 222

lower levels are being proposed in the European community. The fact that
radiographic exposure devices that meet the requirements of ANSI N432,
including the external radiation levels specified, are now on the market,
seems to refute the contention that such devices would be too heavy to
handle. Most portable exposure devices now on the market weigh between
35 and 45 pounds, including those that meet the external radiation levels
of the standard. It should also be mentioned that these radiation levels
can be attained by use of lower strength radiation sources although this
alternative would imply additional costs because of more frequent source
replacements. The provision in the final rule accordingly remains the
same as in the proposed rule.

Section 34.20(b)(1)-Exposure Device Label.

This provision requires the user to attach a label to the radiographic
exposure device that would identify the radionuclide in the device, its
activity on the date specified, its model number and serial number and
the manufacturer of the sealed source.

Comment:

Fourteen comments were received on this provision, with twelve
approving. The negative comments indicated that the upkeep of the market-

M890911.txt

ings could be costly and that the isotope manufacturer must be responsible for providing the label to the user. One commenter proposed that the exposure device label should also include the name, address, and

05/22/89 17 Enclosure A

[7590-01] 223

telephone number of its owner so that the proper persons could be contacted if the device became lost and then found.

Response:

In current industry practice the manufacturer provides a plate to the device user with the source changer and the new source. It is the responsibility of the user to attach the plate containing the prescribed information to the radiographic exposure device. The NRC agrees that it would

be desirable to include the name, address and telephone number of the owner on the label and is including this requirement in the final rule.

It is the responsibility of the user to keep this information current.

No other changes are being made to the proposed rule in regard to this provision.

Section 34.20(b)(2)-Exposure Devices Intended as Type B Transport Containers to Meet Part 71 Requirements.

Comment:

There were no negative comments on this provision. Some commenters mentioned that their devices already met this requirement.

Response:

No change is to be made in this provision.

Section 34.20(b)(3)-Modification of Exposure Devices and Associated Equipment is Prohibited.

05/22/89 18 Enclosure A

[7590-01] 224

Comment:

No negative responses were received on this provision. One manufacturer asked if this implies that no modifications may be made without resubmission of designs to the proper NRC or Agreement State authority .

Response:

The purpose of this provision is to prohibit modifications by users that could compromise the safety of the device. One example would be the use of a source assembly different from that approved by the device manufacturer, and which does not meet the QA and QC requirements of the specified source assembly. This provision is not intended to impose design restrictions on manufacturers. However, manufacturers would need NRC approval of modified designs prior to distribution of the new devices.

The provision stands as originally stated.

Section 34.20(c)(1)-Source Assembly - Control Cable Connection.

The purpose of this provision was to require a coupling between the source assembly and the control cable such that the possibility of an unintentional disconnect could not occur. The recommendation of the equipment task force mentioned previously was that the coupling should require the application of motion in two planes and a positive force in one of these planes to complete the connection.

Comment:

Twenty-two comments were received, fifteen for and seven against the provision. Several commentators from each side indicated that the wording should be changed from technical specifications to performance requirements. They suggested that the wording be patterned after the wording

06/05/89 19 Enclosure A

[7590-01] 225

used in the regulations issued by the State of Texas. Basically these require that the connection shall be designed in such manner that the source assembly will not become disconnected if cranked outside of the guide tube. Most commenters felt that the technical specifications listed in the present wording could prevent designers from developing a connector that would provide the best performance possible.

Response:

This suggestion was adopted and the wording of the provision has been changed to reflect the performance requirement approach used by the State of Texas. Also, NRC's source and device registration process will ensure compliance with this performance requirement by requiring NRC approval before the newly designed connectors could be used.

Section 34.20(c)(2)-Require a Readily Visible Source Position Indicator.

The purpose of this provision was to provide the radiographer with additional or supplemental information concerning the position of the radioactive source. It was not intended as a substitute for the use of a survey meter but rather to provide supplementary information much as does a warning light on the gas gauge of an automobile.

Comment:

Forty-two comments were received on this provision, four approved and thirty-eight opposed the provision. Most of those commenting against it felt that the indicator would not be foolproof, could easily fail, and would lead radiographers to neglect the use of the survey meter. Three commenters stated that the indicators on some of the devices now in use are not completely reliable and have not proven to be fail-safe. Three

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05/22/89 20 Enclosure A

[7590-01] 226

indicated that they did not think it would increase safety. Others pointed out that most indicators only indicated the position of the source assembly and would not be of use if the source separated from the assembly. Two of those approving the provision noted that the position indicator should only be relied upon as a guide.

Response:

This particular item has long been controversial. At a 1978 NRC meeting convened to discuss the design of radiographic exposure devices, it was generally agreed that it was not possible to design a position indicator that could not fail. It was also pointed out at this meeting that source position indicators consisting of red and green lights were installed on some devices as early as 1958. These failed so frequently that the NRC asked manufacturers to remove them. Also, a provision for such an indicator has been proposed for inclusion in the next revision of the International Radiography Standard, ISO 3999, by the French delegation, but there appears to be little support for this from other countries. In view of the continued opposition and past experience with these indicators the NRC has removed the provision.

Note: Proposed paragraph • 34.20(c)(2) has been deleted. It should be noted that proposed rule paragraphs • 34.20(c)(3) through • 34.20(c)(10) as discussed below, are designated as paragraphs • 34.20(c)(2) through • 34.20(c)(9) in the text of the final rule.

Section 34.20(c)(3)-Automatic Securing of Source Assembly.

This provision provides a system to automatically secure the source assembly in the shielded position each time it is cranked back into the

05/22/89 21 Enclosure A

[7590-01] 227

exposure device. The provision eliminates the manual securing which is now required under • 34.22(a) of the current regulations. The provision helps eliminate the problem of the source accidentally moving out of the fully shielded position after it has been cranked back into the device .

Comment:

Thirty-two comments were received on this provision, seven in favor and twenty-five opposed. The majority of those opposed appeared concerned with the additional maintenance needed to keep the automatic securing system operating properly. Four were opposed on the basis of cost. Three pointed out that it could easily be bypassed. One commenter pointed out that existing devices with this provision have failed, and two indicated that the source could be locked outside the device instead of inside.

Several also expressed concern that the provision would discourage the use of the survey meter. One commenter would like to include the option of unsecuring the source remotely.

Response:

The NRC does not agree that the automatic securing provision will cause all the problems raised by commenters. Some of the incidents involving overexposures caused by the source slipping out of its shielded position, are due to failure of the radiographer to manually secure the

M890911.txt

source after each exposure as required by current regulations, or due to excessive wear caused by radiographers using foot operation rather than hand operation in the manual securing. As for the statements regarding by-passing the automatic securing, and discouraging the use of survey meters, the NRC does not believe that many persons will deliberately by-pass or ignore such beneficial measures. Appropriate maintenance, coupled with

06/05/89 22 Enclosure A

[7590-01] 228

- 34.20(a) thru (c) after one year from publication of the final rule in the Federal Register.

Comment:

One commenter requested the compliance not be required for two to two and one half years. Some other commenters expressed doubt that manufacturers could meet the requirements in one year. One commenter noted that there was only one type 1R device for iridium sources and none for 60cobalt sources available in the U.S. at the present time.

Response:

The requirement has been changed to require compliance after one year from the effective date of the final rule.

Section 34.20(e)-All Devices in Use to Comply with • 34.40 After Five Years.

The purpose of this provision is to require that all radiographic exposure devices meet all of the provisions of • 34.20 after five years or be retired from use.

Comment:

Twenty-seven comments were received on this provision, two in favor and twenty-five opposed. Most of the comments objecting to the provis

ion
challenged the average lifetime of five years for the devices, citing
for
the most part a ten to fifteen year lifetime. The other major objecti
on
was the cost, with one commenter citing a value of over \$630,000. One
commenter had reservations about setting a time limit for compliance

06/05/89 28 Enclosure A

[7590-01] 229

especially when working models for some of the provisions have yet to
be
developed and tested. Another stated that there is no projection devi
ce
for cobalt presently available in the U.S. that meets the standard and
that current devices, which cost around \$15,000, would have to be repl
aced
in five years.

Response:

While many of the commenters feel that this provision poses an
excessive financial burden to users and could result in premature repl
ace-
ment of safe and useful equipment, this view is not shared by the NRC.
The
choice of five years was based upon discussions with equipment manufac
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turers and upon NRC experience which indicated that the average lifeti
me of
devices which project a source out of a shielded position is around fi
ve
years. The NRC recognizes, however, that the average life expectancy
is
dependent upon the design of the device, the amount of use, the enviro
nment
at the use site, and the quality of the maintenance program. The choi
ce of
a five year implementation period for the rule rather than a more acce
ler-
ated period was made for a number of reasons. Radiography exposure de
vice
manufacturers would probably be unable to manufacture 3500 devices mee
ting
the requirements of the rule in a much shorter time; the five year per
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M890911.txt

avoids imposing a severe financial impact on the radiography industry, particularly on the small entities; and the number of radiography over - exposures occurring per year does not appear to justify a shorter implementation period.

In addition, the gradual use of new models is advisable since additional training will be required for radiographers, and user licenses need additional time to evaluate new models as they become available to assure that they meet expectations under operational field conditions.

06/05/89 29 Enclosure A

[7590-01] 230

The NRC is aware that retrofitting of existing radiographic exposure devices to meet the requirements of the rule is not practical and that meeting the requirements of the rule involves the purchase of new equipment that meets all the requirements.

The NRC is aware that the radiography industry is in a period of recession and that, as a result, many smaller radiography firms have gone out of business. A side-effect of this depressed state of the industry has been the creation of a large market in used radiographic exposure devices.

The NRC is concerned that many of the devices now in use by the industry may be from 10 to 20 years old. The devices may no longer be in production and replacement parts may not be available. Emphasis of this point is shown by the intent of one of the larger device suppliers to issue a notice phasing out of service, over a period of 3 years beginning in 1989, certain of the devices it normally services because of unavailability of replacement parts. The NRC believes that many other devices with similar problems not subject to this notice are also in use in the market place. This provision will help to phase out of use such un-

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viceable and possibly unsafe devices. While conceding that the lifetime of many devices may be as much as 10 years, the NRC believes that many of the devices currently in use need to need to be replaced with devices meeting the criteria of the rule to protect the public health safety.

With regard to the charge that compliance with the new rule would constitute an excessive financial burden, it should be pointed out that all equipment in use at the time of publication of the proposed rule will have been in service for a period of more than seven years at the date required for compliance, and would therefore also have been eligible for a seven

06/05/89 30 Enclosure A

[7590-01] 231

year application of its depreciation allowance. This allowance would seem to appreciably reduce the financial burden claimed by the commenters. In addition, the regulatory analysis for this rule indicates that the cost to the industry resulting from implementation of this provision of the rule is of the order of \$4 million dollars on a 1989 present worth basis calculated over the ten year interval from 1990 to 1999. The cost to the individual licensee resulting from implementation of this provision of the rule over the same ten year period is \$3636. Annual costs over this ten year period are therefore \$400,000 for the industry and \$364 for individual licensees. In view of these arguments, the provision remains as proposed except that the five year period will begin after the effective date of the final rule.

Section 34.21-Limit on External Radiation Levels.

The purpose of this provision is to allow equipment received prior to

M890911.txt

one year after the effective date of the rule to meet the existing radiation levels of the present • 34.21 now redesignated • 34.21(a). After a period of five years from the effective date of the final rule-, all radiographic equipment except source changers and storage containers will be required to meet the requirements of • 34.20. Source changers and storage containers continue to be regulated under • 34-21(a).

Comment:

Five comments were received on this provision, three approving and two opposed. The principal comments were that reduction of external radiation levels would not be cost effective and that existing levels have not proven to be a radiological health hazard.

06/05/89 31 Enclosure A

[7590-01] 232

Response:

The issue of external radiation levels is extensively discussed in the response to • 34.20(a) and will not be repeated here. The final version of • 34.21 will change from that in the proposed rule to the extent that the requirements will become effective five years after the effective date of the rule rather than five years after publication of the final rule.

Section 34.30-Reporting Requirements.

The purpose of this provision is to provide the NRC with information on problems experienced with radiographic equipment.

Comment:

Sixteen comments were received. six in favor and ten opposed. The principal comments were that item one, involving source disconnects, and item two, involving inability to retract the source, were reasonable reporting items. However, the requirement to report about item three,

M890911.txt

failure of any component to perform its function, was unclear, open ended, and could lead to large volumes of required reports. Other commenters believed that the costs would be prohibitive and still others commented that licensees would simply refuse to comply with these reporting requirements. One commenter felt that reporting of defective equipment should be reported under 10 CFR Part 21.

Response:

The NRC agrees that item three was ambiguous and has rewritten it to apply only to components critical to safe operation of the device. The NRC does not agree with those commenters who believed that a large volume

06/05/89 32 Enclosure A

[7590-01] 233

of reports would be required along with the correspondingly high costs associated with generating such reports. These requirements are separate and distinct both in content and purpose from those contained in 10 CFR Part 21, "Reporting of Defects and Noncompliance" which implements section 206 of the Energy Reorganization Act of 1974, as amended. By specifying conditions for reporting defects or noncompliance of radiographic equipment under this provision any ambiguity resulting from interpretation of Part 21 provisions is avoided.

Section 34.33(a)-Require Wearing of an Alarm Ratemeter.

This provision is intended to provide radiographers in the field with a duplicative or redundant device as a backup to the survey meter the radiographer is supposed to carry.

Comment:

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Fifty comments were received on this provision, eighteen approved. thirty-two were opposed. The principal comments of those approving the provision were that the rule should specify an alarm ratemeter instead of dosimeter, that state-of-the-art chirpers should be allowed, that the trigger level of 500 mR/hr was too high, (this is addressed in • 34.33 (f)) and that they can malfunction and read zero. One commenter felt that there should also be a requirement that the alarm should go off if the ratemeter is subjected to radiation saturation.

Response:

Its purpose is to provide an additional warning of possible hazardous radiation levels in the event the survey meter is defective or misread, in much the same manner that buzzers and lights provide backup warning in

06/05/89 33 Enclosure A

[7590-01] 234

automobiles of low or almost empty gas tanks for those who ignore or misread their fuel gauge. It is felt that as warning devices, alarm ratemeters may be able to prevent many overexposures that have occurred as a result of improper surveys.

06/05/89 33a Enclosure A

[7590-01] 235

Comment:

Thirteen comments were received on this requirement. All thirteen were opposed. The principal comments were that the trigger level was too

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high for most working conditions and that the trigger level was too high to check conveniently on a daily basis without the use of a large check source that would require a specific license. One commenter pointed out that around power facilities 500 mR/hr was too low and recommended a trigger level of 100-200 mR/hr above the ambient background rate.

Response:

Radiographers routinely work with radioactive sources whose activities are sufficient to create high radiation areas (>100mR/hr) and radiographers are required to post the boundaries of the high radiation areas with appropriate signs (• 20.203(c)) and survey the restricted area boundary. Also, calculations based on the inverse square law show that for a 200 Ci Iridium source the radiation field at a normal operator's position (with 21 foot guide tube and 25 foot control tube) is approximately 430 mR/hr. Trigger levels of much less than the 500 mR/hr specified would then trigger an alarm under normal radiography exposures. Also, alarm ratemeters that trigger while radiographers are conducting normal operations would prove annoying and would likely be turned off. In view of these conditions, the trigger level should be set at 500 mR/hr. Those licensees that have a problem with this provision due to the need to work at nuclear power facilities where higher radiation levels may exist, may apply for an exemption under. • 34.51.

With regard to the requirement to check the dosimeter alarm at 500 mR/hr on a daily basis, the provision has been rewritten to require a

05/22/89 36 Enclosure A

[7590-01] 236

calibration on an annual basis instead. The requirement for a daily check on the alarm remains unchanged. This can be provided by an

M890911.txt

electronic check point that corresponds approximately to the response of a 500 mR/hr field.

Modification of Enforcement Policy

The Commission is modifying its General Statement of Policy and Procedure for NRC Enforcement Actions, 10 CFR Part 2, Appendix C (Enforcement Policy) to reflect the Commission's amendment of 10 CFR Part 34.

The change to the Enforcement Policy is being published concurrently with the new rule.

The modification to the Enforcement Policy is being made at this time to Supplement VI "Fuel Cycle and Materials Operations" to put licensees on notice that the failure to implement the requirements for dosimetry and equipment by the required date may be considered a violation of significant regulatory concern. The example is to be used as guidance in considering Severity Level III violations of the requirements. The example for Severity Level III is significant because it represents failures associated with the use of equipment and dosimetry designed to minimize overexposures from radioactive materials.

Finding of No Significant Environment Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule is not a major Federal action

06/05/89 37 Enclosure A

[7590-01] 237

significantly affecting the quality of the human environment and therefore an environmental impact statement is not required.

The final rule involves engineering design modifications to indus-

trial radiography devices and requires licensees to use only radiography devices and associated equipment that provide certain additional safety features. Radiographers are required to wear alarm ratemeters. No requirements for significant quantities of materials, water, electricity or other forms of energy have been identified and no environmental or radiation impacts are involved.

The environmental assessment and finding of no significant impact on which this determination is based are available for inspection at the NRC Public Document Room, 2120 L Street NW., Lower Level, Washington, DC.

Single copies of the environmental assessment and the finding of no significant impact are available from Dr. Donald O. Nellis, Radiation Protection and Health Effects Branch, Division of Regulatory Applications, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492-3628.

Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget, approval number 3150-0007.

Public reporting burden for this collection of information is estimated to average 0.34 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining

06/05/89 38 Enclosure A

[7590-01] 238

the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect

M890911.txt

of this collection of information, including suggestions for reducing this burden, to the Records and Reports Management Branch (P-530), U.S. Nuclear Regulatory Commission, Washington, DC 20555; and to the Paperwork Reduction Project (3150-0007), Office of Management and Budget, Washington, DC 20503

Regulatory Analysis

The Commission has prepared a regulatory analysis on this final rule. The analysis examines the costs and benefits of the alternatives considered by the Commission. The regulatory analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW, Lower Level, Washington, DC. Single copies may be obtained from Donald O. Nellis, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492-3628.

Regulatory Flexibility Analysis

The NRC has prepared a final regulatory flexibility analysis of the impact of this rule on small entities as required by Section 604 of the Regulatory Flexibility Act. The analysis, which is set out in Appendix A of this document, indicates that this rule could have an economic impact of about \$5,113 initially, and \$1,188 annually on each radiography licensee, 90% or more of which are considered to be small entities. These costs are not considered to be overly burdensome in light of the possible benefits derived.

06/05/89 39 Enclosure A

[7590-01] 239

Backfit Analysis

This final rule does not modify or add to systems, structures, components, or design of a facility; the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility. Accordingly, NRC has determined that the backfit rule 10 CFR 50.109 does not apply to this final rule.

Therefore , a backfit analysis is not required for this final rule because these amendments do not involve provisions which impose backfits as defined in 10 CFR 50.109(a)(1).

List of Subjects in 10 CFR Part 2 and 10 CFR Part 34

Part 2 - Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Civil penalty, Enforcement, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalty, Sex discrimination, Source material, Special nuclear material, Violations, Waste treatment and disposal.

Part 34 - Byproduct material, Incorporation by reference, Packaging and containers, Penalty, Radiation protection, Radiography, Reporting and recordkeeping requirements, Scientific equipment, Security measures.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is adopting the following amendments to 10 CFR Part 2 and 10 CFR Part 34:

06/05/89 40 Enclosure A

[7590-01] 240

NW., Lower Level, Washington, DC 20555. A copy of the document is also on file at the Office of the Federal Register, 1100 L Street NW., Room 8301, Washington, DC 20408.

(b) In addition to the requirements specified in paragraph (a) of this section, the following requirements apply to radiographic exposure devices and associated equipment.

(1) Each radiographic exposure device must have attached to it by the user, a durable, legible, clearly visible label bearing the--

- (i) Chemical symbol and mass number of the radionuclide in the device;
 - (ii) Activity and the date on which this activity was last measured;
 - (iii) Model number and serial number of the sealed source;
 - (iv) Manufacturer of the sealed source;
 - (v) Licensee's name, address, and telephone number.
- (2) Radiographic exposure devices intended for use as Type 8 transport containers must meet the applicable requirements of 10 CFR Part 71.
- (3) Modification of any exposure devices and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.
- (c) In addition to the requirements specified in paragraphs (a) and (b) of this section, the following requirements apply to radiographic exposure devices and associated equipment that allow the source to be moved out of the device for routine operation.
- (1) The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must

06/05/89 43 Enclosure A

[7590-01] 241

be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

- (2) The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device.

This securing system may only be released by means of a deliberate operation on the exposure device.

- (3) The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

(4) Each sealed source or source assembly must have attached to it or engraved in it, a durable, legible, visible label with the words: "DANGER - RADIOACTIVE." The label must not interfere with the safe operation of the exposure device or associated equipment.

(5) The guide tube must have passed the crushing tests for the control tube as specified in ANSI N432 and a kinking resistance test that closely approximates the kinking forces likely to be encountered during use.

(6) Guide tubes must be used when moving the source out of the device.

(7) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during radiographic operations.

(8) The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432.

06/05/89 44 Enclosure A

[7590-01] 242

(9) Source changers must provide a system for assuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

(d) All newly manufactured radiographic exposure devices and associated equipment acquired by licensees after (insert a date 1 year from the effective date of the final rule) must comply with the requirements of this section.

(e) All radiographic exposure devices and associated equipment in use after (insert a date 5 years from the effective date of the final rule) must comply with the requirements of this section.

3. In • 34.21 the existing paragraph is designated as paragraph (a) and a new paragraph (b)-is added to read as follows:

• 34.21 Limit on levels of radiation for radiographic exposure devices and storage containers.

* * * * *

(b) Paragraph (a) of this section applies to all equipment manufactured prior to (insert a date 1 year after the effective date of the final rule). After (insert the date 5 years after the effective date of the final rule), radiographic equipment other than storage containers (source changers) must meet the requirements of • 34.20 and • 34.21 applies only to storage containers (source chargers).

4. A new heading "REPORTING" is added and a new • 34.30 is added under that heading to read as follows:

• 34.30 Reporting requirements.

(a) In addition to the reporting requirements specified under other sections of this chapter, each licensee shall provide a written report to

06/05/89 45 Enclosure A

[7590-01] 243

the U.S. Nuclear Regulatory Commission; Division of Industrial and Medical Nuclear Safety; Medical, Academic and Commercial Use Safety Branch; Washington, DC 20555, with a copy to the Director, Office for Analysis and Evaluation of Operational Data, U.S. Nuclear Regulatory Commission, Washington, DC 20555, within 30 days of the occurrence of any of the following incidents involving radiographic equipment:

(1) Unintentional disconnection of the source assembly from the control cable.

(2) Inability to retract the source assembly to its fully shielded position and secure it in this position.

(3) Failure of any component (critical to safe operation of the device) to properly perform its intended function.

(b) The licensee shall include the following information in each report submitted under paragraph (a) of this section:

- (1) A description of the equipment problem.
 - (2) Cause of each incident, if known.
 - (3) Manufacturer and model number of equipment involved in the incident.
 - (4) Place, time and date of the incident.
 - (5) Actions taken to establish normal operations.
 - (6) Corrective actions taken or planned to prevent recurrence.
 - (7) Qualifications of personnel involved in the incident.
- (c) Reports of overexposure submitted under 10 CFR 20.05 which involve failure of safety components of radiography equipment must also include the information specified in paragraph (b) of this section.

06/05/89 46 Enclosure A

[7590-01] 244

5. In • 34.33 paragraph (a) is revised to read as follows and a new paragraph (f) is added to read as follows:
• 34.33 Personnel monitoring.

(a) The licensee may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each such individual wears a direct reading pocket dosimeter, an alarm ratemeter, and either a film badge or a thermoluminescent dosimeter (TLD) except that for permanent radiography facilities where other appropriate alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required. Pocket dosimeters must have a range from zero to at least 200 milliroentgens and must be recharged at the start of each shift. Each film badge and TLD must be assigned to and worn by only one individual.

* * * * *

(f) Each alarm ratemeter must--

- (1) Be checked to ensure that the alarm functions properly (sounds) prior to use at the start of each shift;
- (2) Be set to give an alarm signal at a preset dose rate 500 mR/hr.
- (3) Require special means to change the preset alarm function; and
- (4) Be calibrated at periods not to exceed one year for correct response to radiation: Acceptable ratemeters must alarm within plus or minus 20 percent of the true radiation dose rate.

6. In Appendix A, Item II.C, "Use of personnel monitoring equipment," is revised to include:

Appendix A

II ***

06/05/89 47 Enclosure A